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10/566,829	01/31/2006	Chikara Jin	TOYA145.001APC	7514

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,829	JIN ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *25 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The amendments filed 09/25/2008 were entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. The rejections of claims 1, 3-4 and 8 under 35 U.S.C. 102(b) as being anticipated by *Johnson et al* have been withdrawn in light of Applicant's cancellation and amendment of claims.

4. The rejection of claims 1-5 and 8 under 35 U.S.C. 103(a) as being unpatentable over *Johnson et al* in view of *Hai* and *Fukuchi et al* have been withdrawn in light of Applicant's amendments.

5. The rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over *Johnson et al* in view of *Ninomiya et al* has been withdrawn in light of Applicant's cancellation of the claim.

6. The rejections of claim 7 under 35 U.S.C. under 35 U.S.C. 103(a) as being unpatentable over *Johnson et al* in view of *Zabik and Aldrich* has been withdrawn in light of Applicant's cancellation of the claim.

7. The rejections of claims 1-8 on the ground of nonstatutory obviousness-double patenting over claim 1 and 7 of *Ninomiya et al*, in view of *Johnson et al*, *Fleming et al*, *Quercia et al*, *Hai*, *Zabik and Aldrich*, and *FDA Guidance for Industry* have been withdrawn in light of Applicant's amendments to the claims. Accordingly, Applicant's arguments as to this matter are moot.

8. Applicants' arguments, filed 09/25/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Priority

9. As stated in MPEP 706.02(VI), "The filing date of a foreign priority document is not the effective filing date, although the filing date of the foreign priority document may be used to overcome certain references". Accordingly, Applicant is not entitled to an effective filing date of 07/12/2004, the filing date of a foreign priority document. Applicant is entitled to the effective filing date of the International Application, which is 7/12/2005. That being said, however, Applicants **do** have a priority claim under 35 USC 119(a)-(d) based on the filing date of the foreign priority document on 07/12/2004.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. As amended, instant claim 1 is drawn to a jellied pharmaceutical composition for oral administration, comprising a 5-HT3 receptor antagonist - more specifically, for

example, granisetron (claim 3) - kappa and/or iota-carrageenan, locust bean gum, sodium polyacrylate and water, wherein the composition has a pH of 7 or less. The following rejection is necessistated by amendment.

13. It is unclear from the claim what is meant by the term "or" in the recitation "kappa and/or iota-carrageenan". One interpretation of the claim is that the "or" embodiment requires a selection from one of the first three components: (a) a 5-HT3 receptor antagonist, **or** (b) kappa carrageenan, **or** (c) iota carrageenan. In contrast, another interpretation of the claim is that the "or" embodiment only requires a selection between (b) and (c) - i.e., between kappa and iota carrageenan - and that (a) a 5-HT3 receptor antagonist must be present with either (b) or (c). Accordingly, the meaning of the term "or" is unclear, and a person of ordinary skill in the art at the time the invention was made would not be able to ascertain the metes and bounds of the claim. As such, claim 1 is indefinite. Furthermore, claims 2-3, which fail to clarify the meaning the term "or" are also indefinite.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. **Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Johnson* (US 6,316,027) in view of *Ninomiya et al* (US 5,932,235)**.

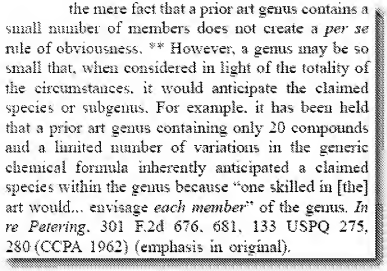
17. As amended, instant claim 1 is drawn to a jellied pharmaceutical composition for oral administration, comprising a 5-HT3 receptor antagonist - more specifically, for example, granisetron (claim 3) - kappa and/or iota-carrageenan, locust bean gum, sodium polyacrylate and water, wherein the composition has a pH of 7 or less. The following rejected is necessitated by the claim amendment.

18. *Johnson et al* teach a composition comprising a 5-HT3 receptor antagonist, (specifically granisetron) a gelatinizing agent (specifically gelatin) and water, (Example 15, Columns 16-17) wherein the composition has a pH of 7 or less, specifically 3.0 (Column 10, Lines 21-23, which is part of Example 1; Column 13, lines 65-68 indicate that the formulations of the remaining examples, which includes Example 15, were prepared using the process described in Example 1). Furthermore, *Johnson et al* teach that "the composition will preferably contain, in addition to the active ingredient, matrix forming agents or carriers... Matrix forming agents or carriers suitable for use in the present invention include... carrageenans" (Column 6, Lines 10-18). Moreover, it would have been obvious to a person of ordinary skill in the art at the time the invention was

made to select carrageenans from the list of preferably included matrix forming agents or carriers taught by *Johnson et al* in view of *Ninomiya et al*. *Ninomiya et al* teach jellied medicinal compositions comprising carrageenan and disclose that "there was found little syneresis among all the jellied compositions... using, as a base, carrageenan" (Column 14, Lines 50-53). Accordingly, a person of ordinary skill in the art at the time the invention was made would have been motivated to select carrageenans from the list of preferably included matrix forming agents or carriers taught by *Johnson et al* in order to prevent syneresis of the composition during dissolution. That is, the skilled artisan would have wanted to prevent the extraction of liquid from the gel formed in step (a) of the preparation of a fast-dispering dosage form to ensure dissolution (Column 10, Lines 12-25) and would have reasonably predicted that the addition of carrageenens would successfully prevent syneresis in light of *Ninomiya et al*.

19. However, *Johnson et al* are silent as to the type of carrageenan used in the composition. Additionally, *Johnson et al* do not specifically teach the inclusion of locust bean gum and sodium polyacrylate as additional matrix forming agents as recited by instant claim 1.

20. It is well known in the art that there are only three types of carrageenan (kappa, iota and lambda). As stated in MPEP 2144.08:



the mere fact that a prior art genus contains a small number of members does not create a *per se* rule of obviousness. ** However, a genus may be so small that, when considered in light of the totality of the circumstances, it would anticipate the claimed species or subgenus. For example, it has been held that a prior art genus containing only 20 compounds and a limited number of variations in the generic chemical formula inherently anticipated a claimed species within the genus because "one skilled in [the] art would... envisage *each member*" of the genus. *In re Petering*, 301 F.2d 676, 681, 133 USPQ 275, 280 (CCPA 1962) (emphasis in original).

See also *In re Schaumann* 572 F.2d 312, 316, 197 USPQ 5, 9 (CCPA 1978). In the instant case, the genus taught by *Johnson et al* contains only three species, two of which are claimed as being useful in the instant invention. Thus, in light of the totality of the circumstances, one of ordinary skill in the art at the time the invention was made would immediately envisage each member of the genus. Moreover, one of ordinary skill in the art at the time the invention was made would have been especially motivated to select kappa carrageenan for use in the composition in light of *Ninomiya et al* who teach jellied medicinal compositions comprising carrageenan. More specifically, *Ninomiya et al* disclose that "carrageenan includes kappa, iota and lambda type... kappa-carrageenan is prefably used" (Column 4, Lines 17-20). The skilled artisan would have been motivated to use kappa-carrageenan in the composition taught by *Johnson et al* in view of *Ninomiya et al* who particularly disclose that kappa-carrageenan is preferable in jellied medicinal compositions.

21. *Ninomiya et al* additionally teach the inclusion of locust bean gum and sodium polyacrylate in jellied medicinal compositions. Specifically, *Ninomiya et al* disclose that among matrix forming agents useful in the composition, "it is preferable to use a base containing carrageenan and locust bean gum... in view of preservation stability" (Column 4, Lines 13-16). Furthermore, *Ninomiya et al* teach that "there was found little syneresis among all the jellied compositions of... Examples... using, as a base, carrageenan, locust bean gum, and sodium polyacrylate" (Column 14, Lines 50-53). Accordingly, the skilled artisan would have been motivated to include locust bean gum and sodium polyacrylate in the composition taught by *Johnson et al* in and effort to enhance preservation stability of the composition as well as to prevent syneresis of the composition (as discussed above).

22. Applicant argues that *Johnson et al* differs from the claimed invention in that the composition taught by *Johnson et al* is freeze-dried to remove water, whereas the instant invention is directed to a jellied composition containing water. Although Applicant is correct that the **final** product taught by *Johnson et al* is different from the jellied composition of the present invention, it remains the case that *Johnson et al* clearly teach a jellied composition containing water (Example 15, Columns 16-17). Furthermore, although *Johnson et al* teach the removal of water to form a solid fast dispersing form, prior to the solidification it would have been obvious to the skilled artisan to use kappa carrageenan and to include locust bean gum and sodium polyacrylate in the jellied composition taught by *Johnson et al* for the reasons discussed above: namely, to ensure preservation stability and prevent syneresis of the

composition formed during step (a) of the preparation of a fast-dispering dosage form (Column 10, Lines 12-25), in view of *Ninomiya et al*.

23. Additionally, although *Johnson et al* do not teach the jellied composition "for oral use" as recited by instant claim 1, Applicant is advised that use limitations within product claims do not carry patentable weight unless the recitation of the intended use of the claimed invention results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the prior art jellied composition taught by *Johnson et al* is capable of oral use.

24. Accordingly, claims 1 and 3 are *prima facie* obvious.

25. **Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Johnson et al* in view of *Ninomiya et al* (US 5,932,235) as applied to claim 1 above, in further view of *Hai* (US 6,767,558).**

26. Instant claim 2 is drawn to the composition of claim 1 further comprising a reductant. As taught by *Hai* (US 6,767,558) "The desirability of providing pharmaceutical formulations in which an oxidation-susceptible active drug ingredient or ingredients are protected against oxidative degradation inherent to prolonged storage is a concept well known to, and appreciated by, one of ordinary skill in the art. Anti-oxidants commonly employed in various pharmaceutical formulations may include, inter alia, vitamin E, ascorbic acid, BHT (butylated hydroxytoluene), BHA (butylated hydroxyanisole), and the like." Since developing pharmaceutical compositions capable

of prolonged storage is desirable, it would have been obvious to a person of ordinary skill in the art to combine a reductant, as taught by *Hai*, with the composition taught by *Johnson et al*. The skilled artisan would have been motivated to include a reductant in the composition taught by *Johnson et al* to enhance stability of the jellied composition prior to its solidification, as well as to ensure that the subsequently solidified fast dispersing form would have enhanced stability. Accordingly, claim 2 is *prima facie* obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-

5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000

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